15

No. 01-188

Supreme Court, U.S.
FILED
SEP 20 2002
OFFICE OF THE CLERK

In The
Supreme Court of the United States

Pharmaceutical Research & Manufacturers of America,

Petitioner,

v.

Kevin Concannon, Commissioner, Maine Department of Human Services, and G. Steven Rowe, Attorney General of Maine,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

AMICUS CURIAE BRIEF OF LEGAL SERVICES ORGANIZATIONS REPRESENTING MEDICAID BENEFICIARIES IN SUPPORT OF NEITHER PARTY

SHELDON V. TOUBMAN*
NEW HAVEN LEGAL ASSISTANCE ASSOC., INC.
426 State Street
New Haven, CT 06510
(203) 946-4811

ANNE SWERLICK
FLORIDA LEGAL SERVICES, INC.
2121 Delta Blvd.
Tallahassee, FL 32303
(850) 385-7900

JANE PERKINS
NATIONAL HEALTH LAW PROGRAM
313 Ironwoods Drive
Chapel Hill, NC 27614
(919) 968-6308

* *Counsel of Record*

September 20, 2002

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

INTERESTS OF *AMICI CURIAE* 1

PRELIMINARY STATEMENT 1

RELEVANT MEDICAID PROVISIONS 2

INHERENT PROBLEMS WITH PRIOR AUTHORIZATION 4

PARTICULAR PROBLEMS CREATED FOR MEDICAID BENEFICIARIES BY THE IMPOSITION OF PRIOR AUTHORIZATION 7

CONCLUSION 13

TABLE OF AUTHORITIES

FEDERAL CASES

Dodson v. Parham, 427 F. Supp. 97 (N.D. Ga. 1977) 8

Goldberg v. Kelly, 397 U.S. 254 (1970) 10, 12

Hernandez v. Medows, Case No. 02-20964, 2002 WL 31060425 (S.D.Fla. Aug. 26, 2002) 6, 12, 13

Kessler v. Blum, 591 F. Supp. 1093 (S.D.N.Y. 1984) 3

Ladd v. Thomas, 962 F. Supp. 284 (D. Conn. 1997) 3

New York City Unemployed and Welfare Council v. Brezenoff, 742 F.2d 718 (2d Cir. 1984) 10

Ortiz v. Eichler, 616 F. Supp. 1046 (D. Del. 1985), aff'd 794 F. 2d 889 (3d Cir. 1986) 10

PhRMA v. Concannon, 249 F.3d 66 (1st Cir. 2001) 14

Schweicker v. Hogan, 457 U.S. 569 (1982) 2, 8, 9

Vargas v. Trainor, 508 F.2d 485 (7th Cir. 1974) 9, 10

Visser v. Taylor, 756 F. Supp. 501 (D. Kan. 1990) ... 4, 12

Weaver v. Reagan, 886 F.2d 194 (8th Cir. 1989) 3

STATE CASES

Jeneski v. Myers, 209 Cal. Rptr. 178 (Cal. Ct. of App. 1985) 4, 12

FEDERAL STATUTES

42 U.S.C. § 1396 3

42 U.S.C. § 1396a 3

42 U.S.C. § 1396a(a)(3) 3, 12

42 U.S.C. § 1396a(a)(8) 3

42 U.S.C. § 1396a(a)(10)(A)(i) and (ii) 8

42 U.S.C. § 1396a(a)(19) 3

42 U.S.C. § 1396r-8(d)(4)(D) 12

42 U.S.C. § 1396r-8(d)(5) 4

FEDERAL REGULATIONS

42 C.F.R.§ 431.200 12

42 C.F.R. § 435.906 3

42 C.F.R § 435.930(a) 3

INTERESTS OF *AMICI CURIAE*

Amici represent low-income Medicaid beneficiaries in two states in which the type of drug formulary scheme with prior authorization/supplemental rebates at issue in this case has been implemented (Florida) or is about to be implemented (Connecticut).[1] These beneficiaries have a direct interest in this litigation because prior authorization, a necessary component of the scheme at issue, can result, and has resulted in other states, in significant restrictions in access to prescription drugs for needy Medicaid beneficiaries. Although PhRMA has purported to represent the interests of Medicaid clients in this litigation, it is clearly motivated not by such concerns but by the profit interests of its members, and therefore it cannot adequately present the concerns of low-income Medicaid clients in the various states where the challenged scheme has been or is soon to be implemented. In addition, given the arguments being made by PhRMA, any decision on the legality of the Maine scheme will likely include an assessment of the impact of that scheme on Medicaid beneficiaries, such that the Court will benefit from hearing their perspective.

PRELIMINARY STATEMENT

This brief does not address the legality or illegality under the Medicaid Act or Commerce Clause of the Maine Rx scheme consisting of supplemental rebates and prior authorization imposed on Medicaid recipients with respect to those drugs manufactured by companies which refuse to pay them. Pharmaceutical manufacturers engage in a variety of practices designed to artificially inflate the prices of prescription drugs. States understandably seek to combat this trend, since a significant and growing proportion of their expenditures under their respective Medicaid programs are for prescription drugs. However, the particular state practice of prior authorization ("PA") has the direct consequence of restricting access to prescription drugs for Medicaid recipients, and the specific scheme at issue intentionally restricts access in order to induce drug manufacturers to pay supplemental rebates precisely to avoid these restrictions.

As the Court has noted, in creating the Medicaid program, Congress recognized that "'these people are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people.' " Schweicker v. Hogan, 457 U.S. 569, 590 (1982), quoting H.R. Rep. No. 213, 89th Cong., 1st Sess., 66 (1965). It is therefore important for the Court to recognize the potential harm to Medicaid clients when PA is imposed without due consideration of the interests, needs and special problems of Medicaid beneficiaries, as well as the protections for such beneficiaries intended by Congress.

To assist the Court, *amici* summarize the basic legal protections for Medicaid clients set forth in the Medicaid Act and describe some of the problems with PA for patients generally. They then discuss the particular problems for Medicaid clients created by PA, particularly as it has been imposed in some other states.

RELEVANT MEDICAID PROVISIONS

Congress adopted the Medicaid program in order to

---

[1] Consent to the filing of this brief has been obtained from both parties to this litigation. No party or counsel for a party in this litigation has contributed to the writing of any part of this brief. No monetary contribution toward this brief has been provided by any entity other than *amici curiae*.

"furnish ... medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services...." 42 U.S.C. § 1396. With that overarching purpose, Congress has imposed strict and detailed requirements on state Medicaid plans in order to protect Medicaid beneficiaries, as set forth in 42 U.S.C. § 1396a. One of these requirements is that each state's Medicaid plan "provide such safeguards as may be necessary to assure that ... care and services will be provided, in a manner consistent with simplicity of administration and the best interests of recipients." 42 U.S.C. § 1396a(a)(19).

Another important requirement applicable to all categories of services under Medicaid is that assistance under the Medicaid program "be furnished with *reasonable promptness* to all eligible individuals." 42 U.S.C. § 1396a(a)(8)(emphasis added). And related to this requirement is the mandate that the state plan "provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness." 42 U.S.C. § 1396a(a)(3). "Reasonable promptness" has long been held to apply to requests for individual services under Medicaid, as well as eligibility for Medicaid at large. See Ladd v. Thomas, 962 F. Supp. 284, 290-91 (D. Conn. 1997); Kessler v. Blum, 591 F. Supp. 1093 (S.D.N.Y. 1984). See also 42 C.F.R. §§ 435.906 and 435.930(a). Thus, in order to comply with these provisions, the administrative procedures of a state, including those with respect to any prior authorization system, must assure prompt access to all covered treatments under a given state's Medicaid program, and, if services are denied, must do so only pursuant to an individualized determination of medical necessity, and in compliance with due process requirements. See Weaver v. Reagan, 886 F.2d

194, 199-200 (8th Cir. 1989); Visser v Taylor, 756 F. Supp. 501, 507 (D. Kan. 1990); Jeneski v. Myers, 209 Cal. Rptr. 178, 189 (Cal. Ct. of App. 1985).

Congress also provided that any system of prior authorization for prescription drugs under a fee-for-service Medicaid program must have specific protections, including a 24-hour turnaround time on all requests for prior authorization, and an automatic three-day supply in emergency situations. 42 U.S.C. § 1396r-8(d)(5). However, as discussed below, these pharmacy-specific protections do not protect the thousands of Medicaid beneficiaries whose requests for non-formulary drugs are denied or who, because of confusion and ignorance of PA requirements, are unable to even initiate the PA process.

INHERENT PROBLEMS WITH PRIOR AUTHORIZATION

Prior authorization for prescription drugs is inherently problematic for patients for several reasons, most of which relate not to the prior authorization process itself, but to the failure of the process to even be initiated, owing to ignorance of the system and its details, among both patients and their doctors. Each of these problems for patients generally, whether or not they are covered under a Medicaid program, is discussed below.

First, Medicaid is not the only health insurance program that applies PA to prescription drugs. Each plan that imposes PA has sharply varying rules as to when it is imposed and how one requests PA. United States General Accounting Office, *PRESCRIPTION DRUG BENEFITS: Impact of Medicare HMOs' Use of Formularies on Beneficiaries*, GAO/T-HEHS-99-171, at 4 (July 20, 1999)(Statement of William J. Stanton before the Special Committee on Aging,

U.S. Senate) (available on line at www.gao.gov). Physicians typically must deal with many health plans to run a practice. Many health plans have their own unique formulary, which is premised in part upon whatever current agreements the plan has made with specific drug manufacturers -- whichever drug is the least expensive in a given classification for that particular plan will tend to be on the formulary; the others in the classification will generally not be on the formulary. Id. at 3-4. Moreover, health plans change their formularies with some frequency (generally, at least quarterly), based on the introduction of new drugs and, more importantly, renegotiation by each plan with the drug companies, based on the availability of new generic products and other issues. The number and sheer length of these drug formularies create enormous difficulty for physicians to keep track of which drugs are on which formularies in any given month or quarter. As a result, it is not uncommon for physicians to prescribe drugs which are not on the formulary of the insurance plan for a particular patient (assuming that the doctor even knows what plan is paying for the prescribed medication at the time it is prescribed) without first requesting the necessary PA.

Second, because patients in any health plan routinely obtain access to prescription drugs by presenting a prescription at the pharmacy, expectations are created that this is the manner in which one should proceed to obtain drugs prescribed by a physician. In fact, this procedure generally works for patients. However, in those cases in which PA is required because the drug is not on the formulary, but such authorization has not previously been obtained, the patient presents the prescription and it is not filled.

Third, when the prescription is denied at the pharmacy due to the lack of PA, this information is often not accurately communicated to patients such that they even know about the

availability of PA, let alone the procedure to obtain it. The way that patients might learn of such authorization requirements is through the pharmacist, who types in the request for PA on his or her computer terminal. This computer is linked to the specific health insurer or HMO's pharmacy benefit management computer system. A "yes" or "no" to payment is automatically provided without any human intervention, based on the computer program run by the pharmacy benefit management company, and the pharmacist can convey to the patient the result so obtained. See Hernandez v. Medows, Case No. 02-20964, 2002 WL 31060425, at *5 (S.D.Fla. Aug. 26, 2002)(Ruling Granting Class Certification). However, often the automatic computerized response indicates a rejection for lack of coverage, without indicating that the drug may, in fact, be obtained through PA. Particularly in this situation, the pharmacist is likely to suggest either out-of-pocket payment for the drug or that the patient contact his or her doctor to obtain a prescription for a different drug. The result is that the patient generally is presented with the choice of either direct payment or receiving no drug at all.

Fourth, because some commercial plans use a "closed" formulary, under which non-listed drugs are simply unavailable, the physician may not know that non-listed drugs are available for Medicaid patients through PA. Even if he or she is aware that a non-formulary drug is available through PA through a particular plan, the physician will often change to a different drug which is on the formulary in order to avoid going through a burdensome PA process, see *Report on Prescription Access Hotline (April 22- June 14, 2002). Final Statistical Report* (Mental Health Association in Michigan and Michigan Association for Children with Emotional Disorders), June 24, 2002, at 1-3 ("Michigan Final Statistical

Report")(Lodging with the Court), see also David Mechanic, *Are Patients' Office Visits with Physicians Getting Shorter?*, 334 New Eng. J. Med., Jan. 18, 2001, at 198-204 (the mean duration of a doctor's office visit in 1998 was 18.3 minutes per patient). In fact, this is a primary goal of the HMOs in using formularies. While in many cases such self-censoring by physicians does not cause patient harm, it can create health problems where the alternative formulary drug is not as effective as the drug that the physician would have prescribed if it were readily available without PA, or it causes side effects or adverse drug interactions not present with the originally prescribed non-formulary medication. Id. at 2.

PARTICULAR PROBLEMS CREATED FOR MEDICAID BENEFICIARIES BY THE IMPOSITION OF PRIOR AUTHORIZATION

The above description of the problems with PA apply to patients generally. However, in the case of the typical middle income enrollee in a commercial HMO, there are several options available to obtain a prescription drug, when the enrollee's plan rejects the pharmacy's claim for payment: (1) he or she can pay up-front to obtain the PA-only drug and try to get reimbursed later; (2) he or she will generally have a sufficient educational level and skills to follow through with the doctor or the insurance company, to obtain authorization for the drug the doctor originally prescribed; (3) after approval is obtained, he or she will have transportation to readily return to the pharmacy to obtain the prescription.

It has been suggested in the course of this litigation that PA is not that burdensome for Medicaid patients, as it is often applied in the commercial employer-based health insurance context. However, the circumstances are significantly different for Medicaid recipients. Collectively, these circumstances

mean that PA creates qualitatively different obstacles to access than for middle-income employer-based insurance participants. Peter J. Cunningham, *Affording Prescription Drugs: Not Just a Problem for the Elderly* (Center for Studying Health System Change), Research Report No. 5, at 4, 7 (April 2002)(hereinafter, "Cunningham")(available on line at www.hschange.org). It is therefore imperative that states proceed with great caution when implementing PA schemes for Medicaid recipients.

First, individuals qualify for Medicaid only if they fall into one of the specific categories of low-income individuals covered by this program. The primary categories under which poor people can qualify for Medicaid are being elderly, blind or permanently and totally disabled, being a pregnant woman, or being a member of a family with minor children. 42 U.S.C. § 1396a(a)(10)(A)(i) and (ii). However, the most basic requirement is that the individual have both a very low-income and very few assets. As this Court has noted, "[i]n structuring the Medicaid program, Congress chose to direct those limited funds to persons who were most impoverished and who – because of their physical characteristics – were often least able to overcome the effects of poverty." Schweicker v. Hogan, 457 U.S. at 590. Over half of adult non-elderly Medicaid recipients, including individuals who qualify because they are in families with minor children, have incomes below the federal poverty level. Cunningham, at 4. For those receiving Medicaid because they are elderly, blind or disabled, in 45 states their income must be at or below 74 per cent of the federal poverty level. The Henry J. Kaiser Family Foundation, *State Health Facts Online*, 50 State Comparisons, Medicaid and CHIP, Medicaid Eligibility Levels for Other Enrolled Groups (available online at http://www.statehealthfacts.kff.org.). Thus, in almost all cases, Medicaid beneficiaries lack the resources to pay up-front at the drug store to obtain a

prescribed drug rejected for lack of PA. See Dodson v. Parham, 427 F. Supp. 97, 108 (N.D. Ga. 1977); Stephen B. Soumerai, et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, New Eng. J. Med., Sept. 8, 1994; 331: 650-655, at 650 (hereinafter, "*Effects of Limiting Medicaid Drug-Reimbursement*"). This means that the Medicaid patient who is denied access at the pharmacy counter to a prescribed medication will walk out, not only without the originally prescribed drug, but with **no drug at all**, in the vast majority of cases.

Second, Medicaid clients are sicker than the general population, with a significantly higher incidence of chronic disease. See Schweicker, 457 U.S. at 590; Vargas v. Trainor, 508 F.2d 485, 489 (7th Cir. 1974); Cunningham at 4. More than one-fourth of adult non-elderly Medicaid beneficiaries have multiple chronic conditions, compared to less than 10% of such individuals with employer-based coverage. Cunningham at 4. Further, it is projected that, between now and 2010, the increase in the Medicaid enrollment rate for the blind and disabled will be twice that for all other enrollees. United States Department of Health and Human Services, *"A Profile of Medicaid, Chartbook 2000"*, p. 18, Figure 1.5 (available online at http://cms.hhs.gov/charts/medicaid/2Tchartbk.pdf.). Since Medicaid patients have a statistically lower level of health, given their poverty and disproportionate representation of individuals with chronic disease. Cunningham, at 4, 7, their health can quickly decline, with the physician who prescribed a drug to arrest such decline not even knowing that his or her prescribed treatment is not being applied. Indeed, previous restrictions on Medicaid beneficiaries' access to prescription drugs imposed in the past by other states have resulted in increased emergency mental

health services and increased institutionalization (often irreversible), both increases incurred at state expense. Soumerai, *Effects of Limiting Medicaid Drug-Reimbursement*; Stephen B. Soumerai, et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, New Eng. J. Med., 1991; 325:1072-1077.

Third, literacy skills are disproportionately lower for Medicaid recipients than for the population at large. See New York City Unemployed and Welfare Council v. Brezenoff, 742 F.2d 718, 722 (2d Cir. 1984). As such, information about the details of PA and how to obtain it is less likely to be effectively communicated to such recipients by a pharmacist who has received a computerized message that a drug cannot be filled and correctly identifies the cause as lack of PA.

Fourth, even if they speak English, receive accurate information from the pharmacist about the PA process, and make obtaining the prescribed drug a priority, Medicaid recipients are much more likely to lack the resources to take affirmative steps to negotiate a complicated PA process after a rejection at the pharmacy occurs, assuming that they are advised of this option by the pharmacist. See Goldberg v. Kelly, 397 U.S. 254, 264 (1970); Vargas, 508 F.2d at 489-90; Ortiz v. Eichler, 616 F. Supp. 1046, 1062 (D. Del. 1985), aff'd 794 F.2d 889 (3d Cir. 1986). Even such basic tasks as making a long-distance phone call to the pharmacy benefit management company are difficult, since many Medicaid recipients lack the resources to make long-distance calls and a substantial number do not even have telephones. If they are employed, they often work in service jobs which will not allow them to take time off during the day to make these necessary calls and receive return calls.

Fifth, more Medicaid recipients lack private

transportation, and are physically disabled, than the general population. They thus encounter significant difficulties in simply returning to the pharmacy to obtain a PA-only drug, even if they are able to negotiate the PA process and PA is finally obtained. The initial trip to the pharmacy may be one that had to be specially arranged; it may be days before they can arrange another to pick up the prescription which is finally authorized.

These special obstacles for Medicaid clients have largely been ignored by states which have implemented PA. The way that the states have so far implemented PA, tied to formularies in particular, has not worked well for Medicaid recipients.

In Florida and Michigan, two states that have implemented PA in order to obtain supplemental rebates, the short history of such implementation has seen a disturbingly wide-spread level of interference with access to basic medical care. For example, low-income Medicaid patients in Florida are routinely turned away at the drug store without access to needed prescriptions, because the prescribed drug was not on the formulary and required PA, and yet the physician, not having known that the drug required PA, simply wrote a prescription for it without seeking PA. According to documents provided by the State of Florida in pending class action litigation filed by Medicaid beneficiaries, with respect to Florida's procedures for PA, as well as its "four brand limit" imposed on these beneficiaries:

> Defendant's own statistics demonstrate that over *35,000 [Medicaid] recipients in a single recent month were denied coverage* of their prescription drugs or the opportunity for a hearing, including *21, 974 recipients who received no drug at all in the same therapeutic*

> *class*. These numbers exclude those recipients who were denied their prescription claims due to the generic substitution payment policy and those who eventually did receive their doctor's prescription after an unknown period of delay.

Hernandez, 2002 WL 31060425, at *3.

In Michigan, doctors who request PA for their Medicaid patients are routinely denied authorization. In response to this experience, patients are often switched by their Medicaid doctors from non-formulary to formulary drugs, even though the second drug is far less effective than the first for that particular individual.[2] Michigan Final Statistical Report at 2. Michigan Medicaid recipients are routinely denied approval for drugs on which they have been stabilized for months or even years, causing deterioration in their health status. For recipients treated with complex medication regimens, denial of even one drug and substitution with another can have immediate adverse consequences because of negative interactions between medications.

In Florida, a federal district court has recently recognized due process concerns in the implementation of PA, as it is required under 42 U.S.C. § 1396a(a)(3) and 42 C.F.R.§ 431.200, et seq., see Goldberg, 397 U.S. at 267-68. As explained in the recent class certification decision in Hernandez:

---

2 Medicaid recipients are entitled to all medically necessary medications, with the exception of a few narrow categories of excluded drugs set forth in federal law. 42 U.S.C. § 1396r-8(d)(4)(D). A client may only be limited to a formulary medication if it is equally effective in treating that particular member's medical condition. See Jeneski, 209 Cal. Rptr. at 189; Visser, 756 F. Supp. at 507.

> With a minor exception, the failure to provide such notice and hearing is uniformly being applied against all members of the Plaintiff class [Florida Medicaid beneficiaries].... Typically, this happens when recipients receive prescriptions from their physicians and then go to a pharmacy to get the prescription filled, and are rejected by a state actor for any number of reasons under Florida's complicated Medicaid law. Such claims are decided immediately by the state actor and the pharmacist receives an electronic message stating whether the drug is covered and therefore whether the claim will be paid, suspended, or denied.... *When coverage is denied for whatever reason, there are no provisions for recipients to receive a written notice in either the Florida Statutes or in the current or proposed administrative rule on the prescription drug coverage.*

Hernandez, 2002 WL 31060425, at *5 (emphasis added).

CONCLUSION

The members of PhRMA have largely brought upon themselves the push by the states to impose prior authorization on their products, as the companies' practices are sharply driving up the states' costs under their respective Medicaid programs. While the states are rightly taking action to address this growing problem, the Court must not lose sight of the fact that the protections for Medicaid beneficiaries provided in the Medicaid Act are designed to protect the health of the most vulnerable members of our society-- not the profits of drug companies.

In its decision below, the First Circuit ruled for Maine,

but cautioned that its decision "was without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirements 'as applied.' " PhRMA v. Concannon, 249 F.3d 66, 78 (1st Cir. 2001). Since that time, several states have in fact implemented supplemental rebate/PA schemes, solely for the purpose of saving money. *Amici* believe it is important for the Court to be aware that, where supplemental rebates have been linked with prior authorization requirements, significant harm has befallen Medicaid recipients. They have been denied reasonably prompt access to prescription drugs because of difficulties inherent in the administration of a Medicaid formulary program which exists in the midst of dozens of similar programs, each with its own unique requirements for authorization of excluded drugs. *Amici* therefore exhort the Court to recognize the special obstacles to health care access facing Medicaid recipients under supplemental rebate/PA schemes and the caution with which states must proceed if they seek to implement such schemes.

Dated: September 20, 2002

RESPECTFULLY SUBMITTED,

SHELDON V. TOUBMAN*
NEW HAVEN LEGAL
ASSISTANCE ASSOC., INC.
426 State Street
New Haven, CT 06510
(203) 946-4811

ANNE SWERLICK
FLORIDA LEGAL
SERVICES, INC.
2121 Delta Blvd.
Tallahassee, FL 32303
(850) 385-7900

JANE PERKINS
NATIONAL HEALTH LAW PROGRAM
313 Ironwoods Drive
Chapel Hill, NC 27614
(919) 968-6308

ATTORNEYS FOR AMICI CURIAE

* *Counsel of Record*